SOCIETY OF TOXICOLOGIC PATHOLOGY

December 3, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket number 00D-1539

Dear Sir,

Attached are comments/suggestions regarding FDA's Draft Guidance for Industry document, 21 CFR Part 11; Electronic Records, Electronic Signatures Maintenance of Electronic Records.

These comments are submitted on behalf of the Society of Toxicologic Pathology. They are being submitted to you for consideration as you formulate the final Guidance document. We hope these comments facilitate the generation of practical and easy-to-follow guidelines for proper electronic records management.

Sincerely,

Clarissa Russell Wilson

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Executive Director

00D-1539 C12

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Guidance for Industry
21 CFR Part 11; Electronic records; Electronic Signatures; Maintenance of Electronic Records

Comments on general considerations for electronic records maintenance:

Preserve the ability to process an electronic record's information throughout its record retention period. This is a nice feature to maintain, but it should not be required since loss of such functionality will not render the record unsuitable for inspection, review, or copying. Loss of such functionality may make it less convenient for someone to sort and manipulate the data, however, the primary goal in records protection should be to preserve information/data, not necessarily to facilitate sorting or manipulating it.

Migration approach to maintaining electronic records.
This section highlights several potential problems and does not provide clear or practical solutions. The document indicates that when migrating records, the automated digital signature verification process will yield a "failure" outcome if the migrated record is in a different format or otherwise not identical in every respect. This means that the contents of the electronic record changed after the record was signed and/or that the signature is not genuine. Determining which occurred will be problematic, rendering the record potentially untrustworthy. A third party will not be able to verify that the record's contents have not changed, so having a third party present during the migration process appears to add little or no value.

Color code changes (as well as font/symbol changes) that could occur during the migration process are also problematic, since they represent changes to the report and could change the record content and authenticity. Having to create electronic record amendments to supplement the migrated electronic record and explain the correlation between old and new color (font/symbol) representations may not be practical because of the amount of documentation and quality assurance work that could be involved. Such requirements may represent barriers that make the migration of electronic records impractical.

General comment on audit trails.
Some comment should be made indicating that audit trials need not be instituted or maintained for electronic histopathology data/records, including migrated electronic histopathology data, until after the histopathology data are locked. The rationale for this is presented in the Society of Toxicologic Pathology Position on Histopathology Collection and Audit Trail: Compliance With 21 CRF Parts 58 and 11, November 15, 2002.

END